Maryland Health Care Commission

Public Informational Meeting
Resubmission of the Atlantic C-PORT Trial: Proposed Non-Primary PCI Study and Review Process

September 26, 2006
4160 Patterson Avenue
Baltimore, Maryland 21215

Meeting Summary

On March 29, 2006, the Atlantic Cardiovascular Patient Outcomes Research Team (C-PORT) submitted a revised proposal to the Maryland Health Care Commission (MHCC) to conduct a comparative study of the safety and efficacy of non-primary (including elective angioplasty) percutaneous coronary intervention (PCI) performed in hospitals without cardiac surgery on-site (non-SOS). This is generally referred to as the C-PORT II study. On September 26, 2006, the Commission held a public informational meeting for hospital representatives and others to review the State Health Plan process for considering research proposals for cardiac services that require a waiver from State Health Plan regulations, and to describe the Commission's approach to reviewing the Atlantic C-PORT II proposal: Elective Angioplasty Project. The proposal and supporting documents are posted on the Commission Website: (www.mhcc.maryland.gov/cardiovascularcare/_cardiovascularcare.htm).

Approximately 40 people attended the meeting, including at least five who participated by telephone. A roster of those participating in the meeting is appended to this report. Following initial remarks, Commission staff responded to comments and questions from meeting participants.

Review of the Maryland State Health Plan Waiver Process – Dolores A. Sands, Chief, Specialty Services Policy and Planning

The Maryland State Health Plan (COMAR 10.24.17) provides for the regulation of cardiac surgery and PCI services in the state; PCI services may only be performed in hospitals that provide on-site cardiac surgery services. COMAR 10.24.17 also establishes policies and procedures, including performance criteria, that hospitals seeking to participate in policy-informing PCI-related research must follow when applying for a waiver from the current policy.

Research proposals falling under the Commission's purview are initially reviewed by staff to determine if they meet the general criteria set forth in COMAR 10.24.17. If the criteria are met, the proposal is referred to a Commission-appointed Research Proposal Review Committee (RPRC) comprised of subject-matter medical and scientific experts from Maryland and other states. Experts in law, health care financing, ethics and other subjects also serve on the Committee. The Committee's charge is to determine the scientific merit of the proposal, the adequacy of the study design and its feasibility and the likelihood that the project will accomplish its scientific objectives.

The findings of the RPRC are transmitted to the Commission's Executive Director, who incorporates this information into a recommendation to the Commission. If the findings and recommendation favor the research project and the Commission approves it, the Commission will establish the criteria by which hospitals may apply for a waiver to COMAR 10.24.17, and will determine how long a waiver will remain in effect.

Approach and Next Steps to Reviewing the Atlantic C-PORT II Proposal – Rex W. Cowdry, M.D., Executive Director, MHCC

The original Atlantic C-PORT II non-primary PCI proposal was submitted to the MHCC in January 2005, and was reviewed by the Commission staff and an RPRC as outlined above. The Committee met in April 2005 to review the proposal and issued its report on August 16, 2005. At the time the Commission's Executive Director was formulating a recommendation to the Commission, the Atlantic C-PORT investigators withdrew the proposal. On March 29, 2006, the investigators submitted a revised proposal for the C-PORT II study (http://mhcc.maryland.gov/cardiovascularcare/submission32906.pdf) that addressed many of the points made by the RPRC. The 2005 proposal and the comments of the RPRC can be found at http://mhcc.maryland.gov/cardiovascularcare/pci_study_review_081605.pdf.

MHCC Research Proposal Review Committees are patterned after those organized by the National Institutes of Health (NIH), where leading physicians and scientists are asked to evaluate a research proposal on its scientific merit alone. MHCC Committees do not debate the question of whether the Commission's public policy decision to support a scientifically valid study is wise – only the question of whether the proposal is scientifically sound and able to produce data to inform future clinical and public policy decisions, in the case of C-PORT II, about elective angioplasty. The review process seeks further to minimize the role of policy opinions in the review by including reviewers from both hospitals with and hospitals without on-site cardiac surgery, as well as nationally recognized experts from outside Maryland.

Because specific issues had been raised about the membership of the Review Committee, the Commission's approach to the review of the revised proposal – including the Committee chair and membership – was discussed with the principal investigator, Dr. Thomas Aversano (Johns Hopkins Medical Institutions). Dr. Aversano preferred to move forward expeditiously and agreed that the Commission should use full membership of the previous Review Committee, because the members were all familiar with the study and could more rapidly judge whether the revisions had addressed the key concerns raised in the initial review.

The charge to the Committee regarding the revised C-PORT proposal was outlined in a letter (http://mhcc.maryland.gov/cardiovascularcare/lettertofaxon.pdf) from the Commission to Dr. David P. Faxon (Vice Chair, Department of Medicine, Brigham and Women's Hospital) acknowledging his agreement to serve as Committee chairman, succeeding Dr. Thomas J. Ryan (Boston Medical Center). All other members of the Committee, including Dr. Ryan, remained on the Committee and received the revised proposal and supporting materials in August; written comments were due on September 22, 2006.

Dr. Faxon will review all comments from Committee members and, in conjunction with Commission staff, determine the next step in the review process. Three possible scenarios are

envisioned. One, the written comments are sufficiently clear and consistent that Dr. Faxon might begin formulating the Committee's recommendation to present as a draft summary to the members for consideration during a decision meeting. Two, the comments are less consistent, but likely to be reconciled through a conference call of Committee members prior to drafting a recommendation. Three, the comments reflect substantial differences among Committee members with regard to the scientific merit of the proposal. In this case, a face-to-face meeting may be necessary for the Committee to formulate its recommendation.

As the Committee works through the scientific review and prepares its recommendation, Commission staff will work with the C-PORT investigators to examine funding issues related to the proposed project. The Executive Director will incorporate the Committee's findings and those regarding project funding into a recommendation to the Commission. The RPRC's recommendation and that of the Executive Director will be released prior to the Commission meeting during which the proposal will be discussed.

In the event that the Commission receives and endorses a positive recommendation, it will establish a waiver process allowing non-SOS hospitals to participate in the study. The Commission will develop criteria that hospitals must satisfy in order to apply for and receive a time-limited waiver. The Commission will seek public input in identifying appropriate criteria by posting the draft criteria for public comment prior to Commission action.

Public Comment and Questions – Respondents: Rex W. Cowdry, M.D.; Pamela Barclay, Director, Center for Hospital Services; Dolores A. Sands

Is there a time line for concluding the review process?
The goal is to complete the process as expeditiously as possible. The first step is for Dr. Faxon to review comments from Committee members and to advise the Commission as to how best to move forward. In addition, the project budget will need to be reviewed. If no additional Committee work is involved and the budget issues are quickly addressed, the entire process should move rapidly, perhaps resulting in a decision by the Commission by the end of the year. If additional Committee work is necessary, the process will take longer; the interval between the receipt of an early version of the first C-PORT non-primary PCI proposal and the meeting of the RPRC was less than three months.

Because two years elapsed between the establishment of the primary PCI waiver program in regulation and the granting of the first waivers, can the current process be streamlined so that Maryland hospitals can participate in the study before patient recruitment ends?
There are certain efficiencies that the Commission will bring to bear on the process, e.g., the budget review can be initiated prior to the completion of the work of the RPRC. However, work cannot begin on developing waiver criteria until the Commission decides whether the proposed research program is scientifically justified and adequately funded. The C-PORT study has begun recruiting patients in a number of other states. Because of the large number of patients needed for the study, it seems unlikely that the MHCC process will jeopardize the ability of Maryland hospitals to participate, should the Commission find the study acceptable.

What are the outstanding budget issues, and will there be opportunity for public comment on the proposal?

The review of the original proposal noted that the budget was substantially less than the budgets for similar clinical studies funded by the NIH. One of the key elements in the current proposal is to obtain complete, accurate and reliable outcome data nine months post-procedure. These data are notoriously difficult and time-consuming to obtain, so the Commission staff will work with the investigators to determine whether the funding is sufficient to permit the successful completion of the proposed research.

The Commission's experience, reflecting the long-standing policies of the NIH, indicates that technical review of a research proposal is best performed by interdisciplinary groups of subject-matter experts who are trained in the design and execution of scientific studies. However, public comment is important to the Commission, particularly as it relates to health care policy. In this case, should the Commission agree to permit non-SOS hospitals to offer non-primary PCI as part of the research initiative, it will actively seek public suggestions and comments regarding the criteria to be used in granting and monitoring waivers to hospitals interested in participating in the study. In addition, the draft waiver criteria will be available to all interested parties during a formal comment period.

There are members of the public who might potentially offer informed and constructive comments on the research proposal. Is there opportunity for them to contribute to the review process?
The scientific review process is intended to engage experts who are familiar with the topic, understand the design and execution of scientific studies, and are sensitive to guarding against the introduction of biases and distinguishing between science and science policy. Opening the door to public comment on the scientific merit of a proposal raises the risk of derailing the peer-review process by comments that blur the line between science and science policy and introduce biases not supported by available scientific evidence. Addressing such extraneous issues distracts Committee members and slows the process.

The Commission also recognizes that the experts serving on the RPRC are knowledgeable about the controversies that permeate the cardiovascular care community. Indeed, these controversies are often reported in the media. As a State agency, the MHCC encourages public comment and invites members of the public to contact Commission staff with their insights and concerns.

If a waiver program is initiated and criteria developed, how will the Commission approach issues such as geographic need, patient preference and physician preference?
These and related issues are those for which the Commission will seek public comment. Hospitals are particularly well-placed to help the Commission understand how people in their service area utilize the available health care resources. Like the existing primary PCI waiver criteria, any criteria that might be established should the non-primary PCI research program be implemented in Maryland will be performance-driven. A waiver program can be expected to include performance standards and outcome measures. Performance and outcome are critical to ensuring that the people of Maryland have access to the best available care at any and all hospitals in the state. For example, the Commission will soon start collecting door-to-balloon time data for angioplasty performed in cardiac surgery hospitals; those hospitals and the hospitals offering primary PCI under the current waiver program need to meet the same standards and achieve similar outcomes.

The Website of the Committee for Safe Angioplasty in New Jersey (CSANJ) indicates that its membership includes three RPRC members, and claims that angioplasty studies performed in hospitals without backup cardiac surgery are unsafe and increase patient risk of death by 38%. Because there is no scientific evidence for this assertion, what steps has the Commission taken to ensure that members of the Review Committee are unbiased?
The Commission has exercised due diligence in establishing the RPRC, working hard to engage qualified experts from Maryland and from other parts of the country. The Commission sought to ensure that the membership reflected the range of perspectives current within the cardiovascular care community. In addition, the decision to ask the same Committee to review the revised proposal was taken in consultation with the principal investigator, Dr. Aversano. He encouraged the Commission to engage the same Committee, given the objectivity of their initial review and their familiarity with the controversies surrounding the proposed research.

The Commission is aware of the information on the Website, and earlier this year received a letter from the chairman of CSANJ indicating that the name of former RPRC Chairman Dr. Ryan, which had been posted on their Website without his permission, had been removed. The Commission has been and continues to be mindful of concerns about Committee member bias, and appreciates that its ultimate decision regarding the proposal may or may not be cast by others as reflecting bias on the part of Committee members. The Commission's transparent review and decision-making processes are intended to reduce the likelihood that its work will reflect biases of its advisors, staff or others.

Additional Information

As the C-PORT II proposal review process moves forward, the Commission will provide updates and other information, including announcements of any subsequent Public Informational Meetings, on its Website. Please bookmark the MHCC Cardiovascular Care Web page to easily access this information - http://mhcc.maryland.gov/cardiovascularcare/_cardiovascularcare.htm.

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Attendance Roster

Laura Burhans, Anne Arundel Medical Center
Michelle Harder, Anne Arundel Medical Center
Barbara Hamilton, Baltimore Washington Medical Center
Mary Lanham, Baltimore Washington Medical Center
Kathy McCollum, Baltimore Washington Medical Center
Sue Ward, Baltimore Washington Medical Center
Randy Komenski, Bon Secours Hospital System
Doug Azar, Calvert Memorial Hospital
Andy G. Cohen, Consultant
Marta Harting, DLA Piper
Sasa-Grae Espino, Doctors Community Hospital
Colleen Herrera, Doctors Community Hospital
Juanita Robbins, Doctors Community Hospital
Susan Wright, Doctors Community Hospital
Cindy Drzewiecki, Franklin Square Hospital Center
Greg Vacek, Franklin Square Hospital Center
Nancy Bruce, Frederick Memorial Hospital
Bridget Plummer, Frederick Memorial Hospital
Jim Williams, Frederick Memorial Hospital
Cindy Shay, Gordon Feinblatt
Barry Rosen, Gordon Feinblatt
Wynee Hawk, Greater Baltimore Medical Center
Annice Cody, Holy Cross Hospital
Pat Miller, Howard County General Hospital
Kathy Guggino, Johns Hopkins Medicine
Pat Cameron, MedStar Health
Vanessa Purnell, MedStar Health
Raymond D. Bahr, M.D., Retired Cardiologist
Nancy Creighton, St. Agnes Hospital
F. Joseph Meyers, St. Agnes Hospital
Sean Flanagan, St. Joseph Medical Center
Richard McAlee, Southern Maryland Hospital
Vanessa Aburn, Union Memorial Hospital
Kristin Feliciano, University of Maryland Medical Center
Donna Jacobs, University of Maryland Medical System

Participating by telephone:
Debra Truxillo, Adventist HealthCare
Karen Doyle, Anne Arundel Medical Center
Michael A. Franklin, Atlantic General Hospital
Patricia A. Supik, Carroll Hospital Center
Kenneth S. Lewis, Union Hospital of Cecil County

Maryland Health Care Commission:
Rex W. Cowdry, M.D., Executive Director
Pamela Barclay, Director, Center for Hospital Services
Dolores A. Sands, Chief, Specialty Services Policy and Planning
Suellen Wideman, Esq., Assistant Attorney General
David A. Neumann, Ph.D., Health Policy Analyst, Advanced